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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,146	09/21/2006	Ephraim Lansky	265/55	1853

44696 7590 10/02/2008

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EXAMINER
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BLAKELY III, NELSON CLARENCE

ART UNIT	PAPER NUMBER
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1614

NOTIFICATION DATE	DELIVERY MODE
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10/02/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/599,146	<b>Applicant(s)</b> LANSKY, EPHRAIM	
	<b>Examiner</b> NELSON C. BLAKELY III	<b>Art Unit</b> 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 28-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 28-54 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Application Status***

Claims 28-54 of the instant application are pending. Claims 1-27 were cancelled pursuant to a Preliminary Amendment filed 08/10/2008.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 28-44, 46, 48, 50, 53 and 54, drawn to a pharmaceutical composition, comprising a physiologically effective amount of a mixture of at least one conjugated fatty acid and at least one polyphenol.

Group II, claim(s) 45, 47, 49, 51, 52 and 54, drawn to a method for the management of diabetes mellitus or atherosclerotic disease, or the treatment of a cell proliferation disorder or obesity.

Group III, claim(s) 54, drawn to a method of making a mixture of at least one conjugated fatty acid and at least one polyphenol.

Instant claim(s) 54 is non-statutory, in that, the claimed invention, as set forth, is not encompassed within one of the statutory classes presented under 35 U.S.C. 101, such as a product/composition, process of use, or process of making. Therefore, the Examiner has considered these possible interpretations of instant claim(s) 54, thereby placing instant claim(s) 54 in all three groups above.

Art Unit: 1614

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

Group II involves a method for the management of diabetes mellitus or atherosclerotic disease, or the treatment of a cell proliferation disorder or obesity. The methodological steps, with regard to novelty, are not shared by Groups I and III; therefore, the special technical feature of Group II is not present in Groups I and III.

Group III involves a method for making a mixture of at least one conjugated fatty acid and at least one polyphenol. The methodological steps, with regard to novelty, are not shared by Groups I and II; therefore, the special technical feature of Group III is not present in Groups I and II.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

With regard to Groups I and II:

Applicant is required to elect at least one conjugated fatty acid and at least one polyphenol.

Applicant is required to elect whether the polyphenol includes a phenolic acid. If Applicant elects wherein a phenolic acid is required, Applicant is further required to elect a disclosed phenolic acid.

Applicant is required to elect whether the polyphenol includes an ellagi-tannin. If Applicant elects wherein an ellagi-tannin is required, Applicant is further required to elect a disclosed ellagi-tannin.

Applicant is required to elect whether the polyphenol includes a flavonoid. If Applicant elects wherein a flavonoid is required, Applicant is further required to elect a disclosed flavonoid.

Applicant is required to elect whether the pharmaceutical composition supplied as an article of manufacture further comprises packaging material and instructions for use in the management of diabetes mellitus or atherosclerotic disease, or treatment of a cell proliferation disorder or obesity in instant claims 46, 48, 50 and 53, respectively.

With regard to Group III, Applicant is required to elect at least one conjugated fatty acid and at least one polyphenol.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

Art Unit: 1614

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

With regard to Groups I and II, at least one fatty acid and at least one polyphenol –

Instant claims 28-54.

With regard to Groups I and II, packaging materials and instructions for use - Instant claims 28-54.

With regard to Group III, at least one fatty acid and at least one polyphenol - Instant claim 54.

The following claim(s) are generic: 28-54.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons.

An international application should relate to only one invention, or if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

The expression “special technical features” is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made

Art Unit: 1614

on the contents of the claims as interpreted in light of the description and drawings (if any). Whether or not any particular technical feature makes a “contribution” over the prior art, and therefore constitutes a “special technical feature”, should be considered with respect to novelty and inventive step.

The common technical feature in all groups is a physiologically effective amount of a mixture of at least one conjugated fatty acid and at least one polyphenol. This composition cannot be a special technical feature under PCT Rule 13.2 because the composition is shown in the prior art.

Schimiedl *et al* (WO03/077930; Abstract) disclose a composition containing at least one quercetine flavonoid in combination with at least one saccharide, which includes short chain fatty acids to stimulate reabsorption of liquid and dissolved electrolyte in the lower intestinal tract. Thus, there is no “special technical feature”, which renders this restriction requirement proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Conclusion***

Art Unit: 1614

Claims 28-54 are subject to a restriction/election of species requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NELSON C. BLAKELY III whose telephone number is (571) 270-3290. The examiner can normally be reached on Mon - Thurs, 7:00 am - 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. C. B. III/  
Examiner, Art Unit 1614

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614